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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,483	08/02/2001	Steven Finkbeiner	UCAL161DIV	7273

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EXAMINER

WINKLER, ULRIKE

ART UNIT PAPER NUMBER

1648

DATE MAILED: 08/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/922,483

Applicant(s)

FINKBEINER, STEVEN

Examiner

Ulrike Winkler

Art Unit

1648

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 July 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☒ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 10-13 and 28-30.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

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Applicant's arguments have been fully considered but are not found persuasive. Applicant's arguments and the Examiners rebuttal are essentially the same of record. The claimed method steps only measure the interaction between a protein having a polyglutamine expansion and an antibody in the presence or absence of an agent. This antibody binding cannot be extrapolated to provide any information regarding the interaction of a polyglutamine expansion protein with a cellular receptor. Neither the specification nor the art has provided any evidence that would indicate the presence of the antibody prevents the disease process in an animal; such a showing would be indirect evidence that the antibody blocks the cellular receptor.

There is no correlation in the prior art or the instant specification which would indicate that a compound that interferes with the antibody binding to the polyglutamine expansion of Huntington would interfere with the binding of the polyglutamine expansion protein to the normal cellular target.

The 1.132 Declaration by Ross Stein has been entered and considered but does not overcome the rejection because the declaration does not actually indicate that the antibody binding to the polyglutamine expansion protein binds in the same place where the cellular receptor binds to the polyglutamine expansion protein. "The antibody that will be used is the in this assay has specific binding for the toxic conformation of the polyglutamine" the toxic conformation of the polyglutamine is the fibril formation i.e. the stacking of the polyglutamine expansion proteins into a large mass through the polyglutamine repeat regions this binding provides no information regarding the binding to the cellular receptor. "It is not unreasonable to assume that the binding site on the antibody might have structural features and binding properties for polyglutamine that are similar to the binding sites on the cellular proteins that mediate the

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toxic effect of the polyglutamine" the declaration only speculates that this could be the case but does not necessarily have to be the case. The declaration does not provide any correlation which would indicate that a compound that interferes with the antibody binding to the polyglutamine expansion of Huntington would interfere with the binding of the polyglutamine expansion protein to the normal cellular target. The declaration only indicates that this could be a possibility.

A compound that interferes with the antibody binding to the polyglutamine expansion protein can act on the antibody alone or it can bind to the polyglutamine expansion protein. However, the instantly claimed method cannot determine to which protein the agents binds, therefore, the claimed method cannot determine if the agent is capable of modulating the interaction between the polyglutamine expansion protein and the cellular target.

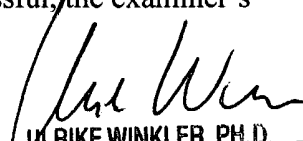
Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989). The Group 1600 Official Fax number is: (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 571-272-0902.


ULRIKE WINKLER, PH.D.
PRIMARY EXAMINER

8/10/04